



WE CLAIM:

1. In combination:

a multipart prosthesis which includes

- (1) a flexible sewing cuff,
- (2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and
- (3) means for securely attaching said prosthesis body to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and
- B) a tool for attaching said flexible sewing cuff to the patient in a minimally invasive manner and which includes
 - (1) a housing
- (2) an operating handle mounted on one end of said housing,
- (3) at least one fastener stored in said housing, said fastener having an elastic limit,
- (4) means for releasably mounting said flexible sewing cuff to said tool, and
- operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit

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2. The tool defined in Claim 1 further including means for separating the tool from the prosthesis.

3. In combination:

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- a multipart prosthesis which includes
- (1) a flexible sewing cuff,
- (2) a prosthesis valve separate from said flexible sewing cuff, and
- (3) means for attaching said prosthesis body to said flexible sewing cuff after said flexible sewing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
 - (1) a housing,
 - (2) an operating handle mounted on said housing,
- (3) at least one fastener stored in said housing, said fastener having an elastic limit,
- (4) means for releasably mounting said flexible sewing cuff to said tool, and
- (5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

4. The tool defined in Claim 3 wherein each fastener includes a tissue-penetrating portion and anchoring means on said tissue-penetrating portion for anchoring said tissue-penetrating after the tissue-penetrating portion has passed through the patient's tissue.

5. The tool defined in Claim 4 wherein the tissue-penetrating portion includes two legs and the anchoring means includes a spring base which is biased to force the legs of the tissue-penetrating portion into a position in which the legs overlap each other.

6. The took defined in Claim 3 wherein the fastener includes a helical portion.

7. The tool defined in Claim 3 wherein each fastener includes a tissue-penetrating portion which includes anti-backup barbs.

- 8. The tool defined in Claim 3 wherein said fastener handling neans includes means for storing fasteners and means for opening fasteners.
- 9. The tool defined in Claim 3 wherein said fastener handling means includes means for storing fasteners and means for imparting rotation to said fasteners.
- 10. The tool defined in Claim 3 wherein said fastener handling



means includes means for storing fasteners and means for A advancing fasteners one at a time.

11. The toof defined in Claim 1 further including means for operating said operating handle which includes a housing; a handle pivotally mounted on said handle; means for translating pivoting movement of said handle into rotational motion; and means for connecting the translating means to a fastener.

12. In combination:

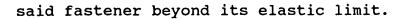
- A) a heart valve prosthesis which includes
 - (1) a flexible sewing cuff,
- (2) a prosthesis valve body separate from said flexible sewing cuff, and
- (3) means for securely attaching said valve body to said flexible sewing cuff after said flexible swing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
 - (1) a housing,
 - (2) an operating handle mounted on said housing,
- (3) at least one fastener stored in said housing, said fastener having an elastic limit,
- (4) means for releasably mounting said flexible sewing cuff to said tool, and
- (5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled



by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

13. In combination:

- A) a multipart heart valve prosthesis which includes
 - (1) a flexible sewing cuff,
- (2) a prosthesis heart valve body separate from said flexible sewing cuff,
- (3) means for attaching said heart valve body to said flexible sewing cuff after said flexible sewing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
 - (1) a housing,
 - (2) an operating handle mounted on said housing,
- (3) at least one fastener stored in said housing, said fastener having an elastic limit,
- (4) means for releasably mounting said flexible sewing cuff to said tool, and
- (5) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming



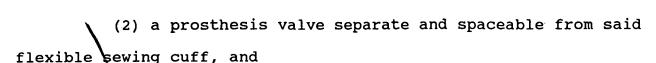
14.\In combination:

a heart valve prosthesis which includes

- (1) a flexible sewing cuff,
- (2) a prosthesis valve separate from said flexible sewing cuff and
- (3) means for securely attaching said valve body to said flexible swing cuff after said flexible swing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
 - (1) a housing
 - (2) an operating handle mounted on said housing,
- (3) at least one fastener stored in said housing, said fastener having an elastic limit, and
- (4) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue from one side of said sewing cuff and the tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

15. In combination:

- A) a heart valve prosthesis which includes
 - (1) a flexible sewing cuff,



- 3) means for securely attaching said valve body to said flexible sewing cuff after said flexible swing cuff has been placed in a patient; and
- B) a tool for placing said flexible sewing cuff in the patient in a minimally invasive manner and which includes
 - (1) a housing,
 - (2) an operating handle mounted on said housing,
- (3) at least one fastener stored in said housing, said fastener having an elastic limit, and
- (4) a fastener handling means on said housing and operationally connected to said operating handle to be controlled by said operating handle for storing said fastener and securing said fastener through said flexible sewing cuff and into the patient's tissue to attach said flexible sewing cuff to the patient without deforming said fastener beyond its elastic limit.

16. In combination:

- A) a multipart prosthesis which includes
 - (1) a flexible sewing cuff,
- (2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and
- (3) said prosthesis valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and
- B) a tool for attaching said flexible sewing cuff to the

patient and which includes

- (1) a housing,
- (2) at least one fastener stored in said housing in a tissue-penetrating shape and having an elastic limit, and
- (3) a fastener handling means on said tool for forcing said fastener into the patient from one side of said flexible sewing cuff and the patient's tissue to attach said flexible sewing cuff to the patient and deforming said fastener beyond its elastic limit into a cuff-retaining shape.

17. In combination:

- A) a multipart prosthesis which includes
 - (1) a flexible sewing cuff,
- (2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and
- (3) said prosthesis valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and
- B) a tool for attaching said flexible sewing cuff to the patient and which includes
 - (1) a housing,
- (2) at least one fastener stored in said housing, said fastener being self-tapping to penetrate the patient's tissue when rotated,
- (3) a fastener handling means on said tool for imparting rotation to said fastener and forcing said fastener into the patient's tissue from one side of the patient's tissue to attach



said flexible \sewing cuff to the patient.

18. In combination:

- A) a multipart prosthesis which includes
 - (1) a flexible sewing cuff,
- (2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and
- (3) said prosthesis valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient; and
- B) a tool for attaching said flexible sewing cuff to the patient and which includes
 - (1) a housing,
 - (2) at least one fastener stored in said housing, and
- (3) a fastener handling means on said tool for forcing said fastener into the patient from one side of the patient's tissue and attaching said flexible sewing cuff to the patient.
- 19. In combination:
- A) a multipart prosthesis which includes
 - (1) a flexible sewing cutf,
- (2) a prosthesis valve separate and spaceable from said flexible sewing cuff, and
- (3) said prosthesis valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient;
- B) a fastener for attaching said\sewing cuff to the patient





from one side of said sewing cuff, said fastener having an elastic limit; and

c) means for forcing said fastener through said sewing cuff and attaching said sewing cuff to the patient without exceeding the elastic limit of said fastener whereby said fastener is non-formed when said sewing cuff is attached to the patient by said fastener.

20. In combination:

- A) a multipart heart valve prosthesis which includes
 - (1) a flexible sewing cuff,
- (2) a prosthesis heart valve separate and spaceable from said flexible sewing cuff, and
- (3) said prosthesis heart valve being securely attached to said flexible sewing cuff after said flexible sewing cuff has been attached to a patient.
- B) a fastener for attaching said sewing cuff to the patient from one side of said sewing cuff, said fastener having an elastic limit and an initial shape; and
- c) means for forcing said fastener through said sewing cuff and attaching said sewing cuff to the patient without exceeding the elastic limit of said fastener whereby said fastener is non-formed and not permanently deformed from the initial shape when said flexible sewing cuff is attached to the patient by said fastener.

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